AMENDMENTS TO THE DRAWINGS

The attached sheets of drawings include changes to Figures 3 and 4D. These sheets replace the original sheets including Figures 3 and 4D. In Figure 3, the previously omitted label for one of the compounds has been inserted. In Figure 4D, the labels for the two identified compounds have been corrected.

Attachment: Replacement sheets (2)
Annotated Sheets Showing Changes (2)

REMARKS

After entry of this amendment, claims 1-5 and 7-25 are pending, of which claims 10-25 are withdrawn. Claim 6 has been cancelled without prejudice or disclaimer, and the subject matter has been incorporated into claim 1. The claims have been amended without prejudice or disclaimer to better comply with U.S. practice, to delete the non-elected subject matter, and to address the various points made in the Official Action. The amended claims find support *inter alia* in the original claims. Further support for the amended claim 1 is found in the original claim 6. Further support for the amended claim 2 is found in the specification at page 14, lines 15-18 and page 19, lines 1-9. No new matter has been added.

In the specification, pages 42, 43 and 47 have been amended adding sequence identifying numbers corresponding to the sequences added to the Sequence Listing to comply with 37 CFR §§ 1.821(a) and (d). Sequences recited in the specification at pages 42, 43 and 47 not appearing in the Sequence Listing previously submitted have also been added to the Sequence Listing attached hereto. No new matter has been added.

Applicants submit herewith a replacement paper copy of the Sequence Listing which conforms to 37 CFR §§ 1.821-1.825, a diskette containing the Sequence Listing in computer readable form, and a Statement to Support Filing and Submission in Accordance with 37 CFR §§ 1.821-1.825. No new matter has been added to the Sequence Listing. Entry of this Sequence Listing into the application is requested.

Specification

The Examiner objects to Figure 3 for missing the label for one of the compounds. Applicants respectfully submit herewith Replacement Sheet containing Figure 3. Annotated Sheet Showing Changes is also attached.

Additionally, while preparing the present response, Applicants noted that the compound labels used in Figure 4D were inadvertently truncated. Thus, Applicants submit herewith Replacement Sheet and Annotated Sheet Showing Changes containing the corrected Figure 4D.

Support for the amendments made in Figures 3 and 4D is found *inter alia* in the Figures 5C and 5D, respectively. Further support is found in the specification at page 50, Table 1. No

new matter has been added. Entry of the Replacement Sheets of drawings is respectfully requested.

Claim objection and Rejection under 35 U.S.C. § 112, second paragraph

In view of the present claim amendments, the objection and the rejection under 35 U.S.C. § 112, second paragraph, are believed rendered moot.

Rejections under 35 U.S.C. § 112, first paragraph

Written description rejection

The Examiner rejects claims 1-6 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement, reasoning that the specification does not provide an adequate written description for the nucleic acid molecules used in the claimed process. The Examiner further asserts that information related to the enzymes used in the claimed method was limited at the time of the invention. Applicants respectfully disagree.

As disclosed in the specification, the present invention relates to an improved process for the specific production of polyunsaturated fatty acids using a unique combination of known nucleotide sequences in plants. The claims are not drawn to nucleic acid sequences of the genes *per se*, and thus do not concern a new nucleotide sequence of unknown structure. Rather, the claimed process uses nucleotide sequences with known nucleotide structure and known enzymatic function, and combining them to achieve the production of desired polyunsaturated fatty acids of the present invention.

The nucleotide structure of the nucleotide sequences used in the claimed process is known in the art. As described in the specification, at page 3, line 10, Δ-5 and Δ-8-desaturases are disclosed in WO 00/34439. Other Δ-8-desaturases are also published in Wallis and Browse (Archives of Biochem. and Biophysics, 1999) or available under Genbank Accession No. AF139720/AAD45877. See Specification at page 42, lines 27-32. Similarly, other Δ-5-desaturases are also available in the art at the time of filing. For instance, Δ-5-desaturases have been isolated from various organisms such as *Mortierella alpina* (Michaelson *et al.*, J. Biol. Chem., 1998, 273: 19055-19099), *Dictyostelium discoideum* (Saito *et al.*, Eur. J. Biochem., 1999, 265: 809-814), *C. elegans* (Watts *et al.*, Arch. Biochem. Biophys., 1999, 362:175-182),

and human (Leonard *et al.*, Biochem. J., 2000, 347 (Pt 3): 719-724). Likewise, Δ-9-elongase is also known in the art as disclosed in Qi *et al.* (FEBS Lett., 2002, 510: 159-165).

The enzymatic function of the nucleotide sequences used in the claimed process is also known in the art. As disclosed in the specification, Δ-8-desaturase is known to introduce into C20 fatty acids a double bond in Δ-8-position and Δ-5-desaturase is known to introduce into fatty acid molecules a double bond in Δ-5-position. Specification at page 9, lines 13-15. Similarly, Δ-9-elongase is known to elongate C18 fatty acids with a double bond in Δ-9-position. Specification at page 9, lines 11-13.

Thus, it is respectfully submitted that the specification, together with the knowledge in the art at the time of filing, sufficiently exemplifies the enzymes which are used in the claimed method. This is a proper means of complying with the written description requirement as found in *Ex parte Altenbuchner*. 2007 WL 1766992 (copy attached). In *Ex parte Altenbuchner*, claims drawn to a microorganism transformed with three known enzymes were rejected for failing to comply with written description requirement. The Board reversed the rejection and held that, where the claims were prepared from known DNA sequences of known enzymatic function, written description requirement was met even the specification does not reiterate the structure of the claimed genus of known enzymes. *Id.*, at 4 ("Appellants are not claiming to have discovered the DNAs recited in claim 17; they are prepared from known DNA sequences of known function").

Similar to *Ex parte Altenbuchner*, Applicants are not claiming the nucleic acid sequences encoding Δ-5-desaturase, Δ-8-desaturase, and Δ-9-elongase. Rather, the present claims are drawn to a process using enzymes which were known and characterized in the art at the time of the filing. For these reasons, it is respectfully submitted that specification provides adequate written description and that the PTO has not presented a *prima facie* case showing a lack of sufficient written description. Reconsideration and withdrawal of this rejection is respectfully requested.

Enablement rejection

The Examiner further rejects claims 1-9 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an enabling disclosure, reasoning that the specification does not reasonably

provide enablement for any transgenic organism expressing any Δ-9-elongase and any Δ-8-desaturases. The Examiner further asserts that undue experimentation would be required for one skilled in the art to practice the present invention. Applicants respectfully traverse.

First, please note that "organisms" is changed to "an oil producing plant" in the pending claims. As discussed above, genes of each type are known in the art. Furthermore, the specification provides detailed guidance on how to identify and isolate structural genes and their functional homologs for the use in the claimed process for production of polyunsaturated fatty acids. For instance, Example 3 describes the isolation of Δ-8-desaturase by PCR amplification. Other routine techniques such as hybridization can also be used. Specification at page 15, lines 13-14. Furthermore, the specification describes that conserved regions of the structural genes can be determined by sequence comparisons with other desaturase or elongase genes. Specification at page 15, lines 19-20. For example, the art-recognized "histidine box sequences" are described to be advantageous for isolation of the structural genes useful for the claimed process. Specification at page 15, lines 20-21. This is further illustrated by Saito *et al.* (Eur. J. Biochem., 2000, 267: 1813-1818, a copy is attached), in which a second *Dictyostelium discoideum* functional Δ-5-fatty acid desaturase was identified *via* searching a cDNA data bank with the conserved histidine box sequences.

Additionally, the assays useful for determining the enzymatic activity of the structural genes are known in the art. For instance, Browse *et al.* ("Browse," US 6,825,017, cited by the Examiner in the § 103 rejection below) describes the assays suitable for determining Δ-5 and Δ-8-desaturase activity. See Browse, Col. 6, lines 58-67. Similar techniques can be used for determining the activity for Δ-9-elongase as well. Moreover, Examples 5, 6 and 7 provide methods for generating transgenic plants expressing the structural genes and Examples 10 and 11 provide methods for analyzing fatty acids compositions in such transgenic plants. Taken together, it is respectfully submitted that one skilled in the art would recognize that screening and testing for Δ-5-desaturase, Δ-8-desaturase, and/or Δ-9-elongase activity is routine and is not undue experimentation. See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)(routine screening of hybridomas was not "undue experimentation;" the involved experimentation can be considerable, so long as "routine"). It is further submitted that the detailed guidance provided in

the present specification and the routine nature of the screening for screening and testing overcome the unpredictability alleged by the Examiner.

In view of the teaching of the specification, there is no reason to doubt operability of the process using any functional Δ-5-desaturase, Δ-8-desaturase, and/or Δ-9-elongase.

In view of the detailed description, guidance, working examples, and high level of skill, the specification enables the full scope of the claims without undue experimentation. On these facts, an analysis under *In re Wands* supports enablement.

Rejections under 35 U.S.C. § 103

Claims 1-9 are rejected as being obvious over Mukerji *et al.* ("Mukerji," US 6,677,145) in view of Browse.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. See MPEP § 2143.03. It is submitted that Mukerji and Browse, alone or in combination, do not disclose or teach all the claim limitations.

Mukerji discloses a mouse elongation enzyme MELO4. See Mukerji, Fig. 55. According to Mukerji, MELO4p involves in the elongation of C20 and C22 long-chain PUFAs in n-6 and n-3 fatty acid pathways. Mukerji, Col. 54, lines 7-13. MELO4p is further characterized as a mouse Δ-5-elongase. See Frøster *et al.* (WO2005/118814), page 15, wherein SEQ ID NO: 28 corresponds to SEQ ID NO: 5 of Mukerji. As known in the art, Δ-5-elongase elongates C20 fatty acids but not C18 fatty acid, and Δ-9-elongase elongates C18 fatty acid but not C20 fatty acid. Thus, Mukerji does not teach a Δ-9-elongase.

Browse teaches a Δ-5-desaturase and a Δ-8-desaturase, and their use in the production of polyunsaturated fatty acids using transgenic plants and yeast.

It follows that, the references, when combined, teach at the most the use of Δ-5-elongase, Δ-5-desaturase and a Δ-8-desaturase for the production of polyunsaturated fatty acids using a transgenic organism. The references, alone or in combination, do not teach the claimed process using Δ-9-elongase, Δ-5-desaturase and a Δ-8-desaturase for the production of polyunsaturated fatty acids. Therefore, Mukerji and Browse, alone or in combination, do not render obvious the

subject matter of claims 1-9. Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims.

Applicants reserve all rights to pursue the non-elected claims and subject matter in one or more divisional applications.

Accompanying this response is a petition for a one-month extension of time to and including November 11, 2007, to respond to the Office Action mailed July 11, 2007 with the required fee authorization, including the fee for extra claims. No further fees are believed due. If any additional fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13478-00001-US from which the undersigned is authorized to draw.

Respectfully submitted,

By 

Hui-Ju Wu, Ph.D.
Registration No.: 57,209
CONNOLLY BOVE LODGE & HUTZ LLP
1007 North Orange Street
P.O. Box 2207
Wilmington, Delaware 19899
(302) 658-9141
(302) 658-5614 (Fax)
Agent for Applicants

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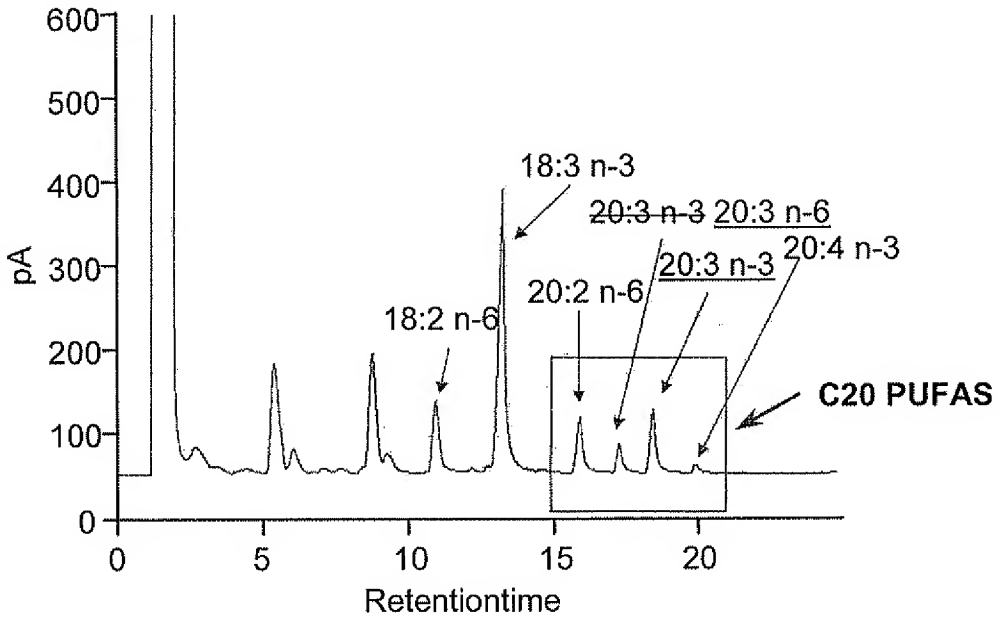
Attachment:

1. Saito et al., A second functional Δ-5 fatty acid desaturase in the cellular slime mould Dictyostelium discoideum, Eur. J. Biochem., 2000, 267: 1813-1818.
2. *Ex parte Altenbuchner*, 2007 WL 1766992.

Annotated Sheet Showing Changes (Figure 3)

FIG.3



Annotated Sheet Showing Changes (Figure 4D)

FIG.4D